AMENDMENT OF NIAID SOLICITATION
"In vitro and Animal Models for Emerging Diseases and Biodefense"

Solicitation Number:	RFP NIH-NIAID-DMID-03-39
Amendment Number:	Two (2)
Amendment Issue Date:	Wednesday, January 15, 2003
Proposal Intent Response Sheet Due Date:	Monday, December 30, 2002
Proposal Due Date: (CHANGED)	**Tuesday, February 4, 2003 at 4:00 PM Local Time**
Issued By:	Paul D. McFarlane Senior Contracting Officer NIAID, NIH, DHHS Contract Management Branch, DEA 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
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This amendment is issued to all potential Offerors.

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS BEEN EXTENDED**. Offerors must acknowledge receipt of this and all other amendments, by identifying this amendment number (and any others) on each copy of any offer(s) submitted. Failure to receive your acknowledgement may result in the rejection of your offer. If, by virtue of this amendment, you wish to change an offer already submitted, such changes may be made by telegram, letter or e-mail, provided each telegram, letter or e-mail makes reference to this solicitation amendment number and is received prior to the opening hour and date specified. Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

PURPOSE OF AMENDMENT: This amendment revises and adds text in several parts of the solicitation and extends the proposal due date to Tuesday, February 4, 2003 at 4:00 PM Local Time.

1. In the RFP section titled, BACKGROUND/ STATEMENT OF WORK/NOTES TO OFFERORS, under CONTRACT TYPE, the four paragraphs provided in Amendment #1, dated December 18, 2002 are deleted and replaced with the following six paragraphs:

This solicitation contains six (6) generic Parts, lettered A, B, C, D, E, and F. Offerors may submit a proposal for one or more of these generic Parts. **Each Generic proposal must be separate, by Part and must contain a technical portion and a business portion.** For Parts A and B, Offerors should propose as many organisms or groups of organisms as possible. Within Parts C and D Offerors may submit proposals for one or more of the models using the same organisms/disease or models for more than one organism/disease. Offerors for Parts E and F should propose comprehensive services to cover all aspects of those Parts. Offerors must also address the requirements of the "General Statement of Work for all Parts" in each generic (Parts A – F) proposal they submit.

In addition to the six generic Parts, this solicitation contains twelve (12) separate Task Orders. Ten were issued with the original solicitation and two were issued with Amendment #1. The distribution of tasks to each generic Part is as follows: Part A has Task A (1), Part B has Task B (1), Part C has Tasks C (1), C (2), and C (3), Part D has Tasks D (1), D (2), D (3), and D (4), Part E has Tasks E (1) and E (2), and Part F has Task F (1). Note that, in addition to the submission of one (or more) proposals for any generic Part, Offerors are required to submit a separate proposal (containing a technical portion and cost portion) for one (or more) of the Task Orders under the generic Part for which they propose. Offerors must also address the requirements of the "General Statement of Work for all Parts" in each task order proposal they submit.

Award of multiple Indefinite Delivery – Indefinite Quantity (IDIQ) type contracts is planned. Each contract will have a seven (7) year ordering period. An IDIQ contract provides for an indefinite quantity (within stated limits) of supplies or services to be furnished during a fixed period, with deliveries or performance to be scheduled by placing task orders with the contractor. It is anticipated that multiple awards will be made for each of the six generic Parts (A through F) of this solicitation. Should an Offeror receive an award for more than one Part, these awards will be combined into one contract. Contractors will be designated as prequalified "Pools" of potential Offerors for each Part (i.e. Part A Pool, Part B Pool, etc.) and will be eligible to receive future task order solicitations for their designated Parts.

NIAID intends have the generic proposals subjected to a scientific/peer review and to evaluate the specific task order proposals for those parts as well. Thereafter, NIAID will establish six (6) separate competitive ranges; one for each of the generic Parts. The competing Offerors' individual business proposals (submitted in response to the generic Parts and to the tasks) will be subjected to a cost analysis during negotiations. Awards will be made to those Offerors determined to offer the best overall value to the Government for one or more of the generic Parts for which they propose and are found technically capable. Contract awards will be made to all Offerors qualified in each pool for the guaranteed minimum amounts of each generic Part. See the "guaranteed minimums" below. It may be necessary for NIAID contract staff to contact and negotiate certain terms of the task order with some or all Offerors. It should be understood that NIAID might not award any task orders to some Offerors qualifying for a given generic Part before September 30, 2003. If such should be the case, any Offeror who makes the competitive range for a given Part, for which no task order is available, will be entitled to invoice for the guaranteed minimum amount(s) for those generic Part(s) for which they qualify, but have not been awarded a task order by September 30, 2003. NIAID reserves the right to issue future solicitations to expand the pools for each generic Part as necessary throughout the seven (7) year ordering period of this requirement. In accordance with HHSAR 352.232-75 INCREMENTAL FUNDING (JAN 2001), NIAID reserves the right to incrementally fund task orders issued under this requirement.

In accordance with FAR Part 16.504(a)(4), for this IDIQ contract, NIAID intends to issue task order solicitations under this contract (beyond the initial awards to result from this solicitation) as needs arise. When requirements are established by the NIAID for any of the products or services within this contract's six generic Parts, specific task order solicitations will be written and issued to one or more Contractor(s) qualified under the pertinent Part(s). The Contractor(s) will be required to prepare and submit a detailed proposal with milestones to perform the task order together with a detailed budget proposal. In the event that there are multiple Contractors under any generic Parts, each Contractor will be given a fair opportunity to compete for the task order awards. The resulting task order awards will include specifics on deliverables and reports. Due to the fact that all Contractors for each Part (i.e. within each pool) will be pre-qualified by virtue of the initial scientific/peer review of their capabilities, there will be no further peer review required for award of the task orders. In accordance with FAR 16.505(b)(1), it should be understood that individual task order proposals submitted by Contractors will be subjected to a technical evaluation, whereby NIAID Program and Contracts staff will ensure that the proposed efforts fit within the "original" capabilities of the Contractor as evaluated by the original Scientific/Peer review panel. Only the Contract Management Branch (CMB), NIAID will be authorized to issue task order solicitations, negotiate terms, and award task orders under this requirement.

The following scale sets forth the guaranteed minimum dollar awards per Part. Note that where the "actual" task order is priced at less than the stated minimum, that actual lower amount shall be awarded.

Part A $ 75,000 Part B $ 75,000 Part C $100,000 Part D $150,000 Part E $100,000 Part F $100,000

2. Under the RFP section titled, BACKGROUND/STATEMENT OF WORK/NOTES TO OFFERORS, INTRODUCTION, the second paragraph is hereby deleted and replaced with the following: (Note this paragraph was also replaced by Amendment #1. The last sentences of this paragraph have been amended, so the entire paragraph is being replaced again by this Amendment #2.)

The objective of this contract is to provide a range of developmental resources to bring new therapies and preventive measures from the laboratory to initial clinical testing in humans. The contract consists of six parts, listed below, which each contribute to the overall development effort. These contracts will provide a ready capacity in a number of needed areas and will be utilized as products become available for testing. Test articles that are found to have activity in Part A may progress through development using contractors from other parts. For Parts C, D, E and F, various vaccine concepts may be tested based on the following categories: (a) synthetic peptides, (b) recombinant subunits, (c) vector based vaccines, (d) virus-like particles/replicons, or (e) nucleic acid based vaccines. This acquisition will also provide some reimbursement for equipment and renovations of contractors' BSL-3 facilities directly related to the requirements of these contract efforts. This is NOT to be construed as "construction" reimbursement. NIAID is limiting this reimbursement to $200,000 for Parts A and B, $300,000 for Part C, $400,000 for Part D. There is no such reimbursement allowed for Parts E and F since these activities are not expected to deal with samples or animals that are infected with Category A, B, or C priority organisms.

3. Under the RFP section titled, BACKGROUND/STATEMENT OF WORK/NOTES TO OFFERORS, STATEMENT OF WORK, PART C: SMALL ANIMAL MODELS FOR SELECTED PATHOGENS INCLUDING GLP STUDIES, the generic Part C statement of work is hereby revised as follows:

PART C: SMALL ANIMAL MODELS FOR SELECTED PATHOGENS INCLUDING GLP STUDIES

The third activity area to be supported under this contract is the development, validation and use of various small animal models to screen new therapeutic, diagnostic and preventive agents or test the efficacy of therapeutics, immunotherapies, diagnostics, and vaccines with activity against emerging infectious agents including, Bioterrorism Category A-C agents. These contracts will provide a ready capacity in a number of needed areas and be utilized as products become available for testing. Other studies such as disease pathogenesis and natural history are not intended for this contract. In vivo safety testing, pharmacokinetics, pharmacodynamics, and toxicity testing are covered under Part E and F of this solicitation. Models for testing of Rift Valley Fever vaccine, Plague vaccine, and screening of currently licensed and marketed antibiotics for anthrax and pneumonic plague are a priority for the NIAID. Offerors are also encouraged to propose models for other important emerging and/or rare viral and bacterial agents as well. Not intended for this solicitation are animal models for infection with Variola major (human smallpox), Filoviruses, and Viral Hemorrhagic Fever agents specifically: Punta Toro, Pichinde, Benzi, and Semlicki Forest viruses, TB, influenza, and botulinum toxin.

Independently, and not as an agent of the government, the Contractor shall develop small animal models to be used for screening and efficacy testing of new products including therapeutics, immunotherapies, diagnostics, and vaccines. Conduct all in vivo testing as are required for approval of a product for human administration. Testing must be sufficient to meet requirements for Investigational New Drug (IND) filing.

Specifically, as directed by the Project Officer, the contractor shall:

1. Utilize or provide one or more well-characterized and validated animal models(s) of human infection and/or disease mediated by Category A-C disease agents to evaluate candidate diagnostics, drugs, vaccines and immunotherapies for preliminary efficacy. (A validated model is one that has shown correlation of results with human clinical trials or trials conducted in NHP, or with the natural history of human infection and is suitable to provide data relevant for obtaining FDA approval for an IND, licensure, or specific indication. The Project Officer will provide guidance for these models.) For infection models, the infection of animals should be efficiently established. For other models, for example, mice transgenic with the human virus receptor gene or mice implanted with virus-infected human tissues, provide and use animals for evaluation of candidate therapies. For all models, the process and dosage level of infection and challenge and/or disease pathogenesis should resemble the corresponding human disease as closely as possible. Standardized protocols, when provided by the Project Officer, shall be incorporated.

2. Perform pre-clinical evaluations of experimental therapies, diagnostic, and preventive agents for infections as specified by the Project Officer. The test agents shall be evaluated for efficacy. When appropriate, conduct studies to evaluate novel strategies for drug delivery and dosing, including combination and sequential drug administration. These studies shall include appropriate uninfected and untreated controls and may involve aerosol challenge of some agents requiring specialized testing facilities. Federal guidelines for care and use of laboratory animals must be followed as well as requirements for approval of animal use protocols. Unless directed otherwise, submit each proposed protocol/experiment/effort to the Project Officer for review, prioritization, and approval. The NIAID Project Officer will provide agents for evaluation. Some, but not all studies will require that they be performed in accordance with Good Laboratory Practice (GLP) regulations. Evaluation capabilities of the animal model shall include, but not be limited to, the following:
a. Quantitative assessments, which detect differences, with at least a minimal level of statistical confidence, between treatment groups of animals, with specific indicators including confirmation of infection, quantitation of organisms present in tissues of infected animals, markers of disease progression, and selected indicators of morbidity.
b. Microbiological and histological analyses, including but not limited to special stains and cultures, to document the purity, severity, pathology, and location of the animal infection. Necropsy/pathology support shall be available as needed.
c. Appropriate observations and measures of general toxicity, to include body weight, blood chemistries, hematologic measures, body temperature, behavior, and other indicators of general health.
d. Immunogenicity and/or immune responses when appropriate for the test article.
e. Limited pharmacokinetic determinations. Offerors will be required only to have the capability of collecting and preparing blood, cell, and tissue samples for shipment to another site for analysis.

3. Perform further studies to characterize and refine the proposed model(s) and to develop new models. The contractor may be required, as directed by the Project Officer, to use animal models other than the one proposed if well-characterized animal models become available. As directed by the Project Officer, develop and evaluate new assays and models that may be required for new/emerging agents and models.

4. Conduct work with animals in accordance with NIH guidelines for animal care and use. Maintain awareness of evolving regulatory requirements for animal research and with the FDA regulatory guidelines for animal studies in support of licensure, such as the 21 CFR Parts 314 and 601 "New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical of Feasible." When efficacy studies are intended to support the clinical use of a test article in humans, the contractor shall also:
a. Provide all data, information, and records required for the writing and submission of the Masterfile, Investigators Brochure, and all other documents related to IND submission and maintenance to the Project Officer or to a designated third party.
b. Retain all records, samples, histopathological slides, etc. and make them available as directed by the Project Officer and as indicated under GLP guidelines.
c. Maintain awareness of evolving regulatory requirements for preclinical toxicologic evaluations for chemicals or biologics, and develop new test systems or models as required to meet new needs.
d. Participate as necessary in discussions with the FDA during pre-IND, IND, and pre-NDA meetings.

Under the Notes To Offerors Organized by RFP Part, General Statement of Work for All Parts, NOTE #1 TO ALL OFFERORS is deleted and replaced with the following. (Note that this paragraph was replaced by Amendment #1. However, it has since been changed, so it is again being issued as part of Amendment #2.)

[NOTE #1 TO ALL OFFERORS: All Offerors that receive an award for one or more of the generic Parts are eligible for, at least, the guaranteed minimum amount for that Part(s). At the time of award, all Offerors that receive an award will receive a contract identifying the guaranteed minimum for their Part(s), plus any additional amounts over the minimum for any task orders awarded with the basic contract. If the first task order awarded is less than the guaranteed minimum, the Offeror(s) will receive that lesser amount. Offerors that receive awards for models of more than one organism or more than one model within a part (as in generic Parts A, C or D) will be eligible for a single minimum award for that Part. It is anticipated that the maximum total funding available will be between $25 - 40 million per year for all contracts.]

4. Under Section L- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS at COMPARATIVE IMPORTANCE OF PROPOSALS, the paragraph is deleted and replaced with the following: (Note that this paragraph was replaced by Amendment #1. However, it has since been changed, so it is again being issued as part of Amendment #2.)

You are advised that paramount consideration shall be given to the evaluation of Offerors' technical proposals, whether provided as a generic proposal for any Part or as the technical proposal for any task order. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make awards to the best advantage of the Government, cost and all other factors being considered.

5. Under Notes To Offerors Organized by RFP Part, PART C: SMALL ANIMAL MODELS FOR SELECTED PATHOGENS INCLUDING GLP STUDIES, NOTE C-1 is revised to read as follows:

[NOTE C-1 TO OFFEROR: The purpose of this solicitation is to obtain animal model systems to evaluate the clinical potential of experimental agents and to facilitate the entry of these agents into human clinical trials. The model system(s) employed should have features similar to the corresponding infection in humans and these should be described. The pathologic and immunologic aspects of the model in association with infection should be discussed in detail and relate to the ability to use this model to predict clinical effectiveness of experimental agents. If a non-infection model is proposed the Offeror should explain in detail why the model is suitable. The infectious agent should be either a human infectious agent or an animal agent with considerable homology to the comparable bioterrorism agent. Background, history and available data that correlate with data produced by the model with regard to comparison with human disease/protection should be provided. Documentation of availability of animals and animal holding space must be included. Offerors should have capacity to house a minimum of 1000 rodents and/or 200 non-rodent small animals concurrently; capacity in excess of this requirement is strongly suggested, and may be through documented access of off-site facilities or subcontracts. Capability to perform aerosol challenge studies should be included. For the purposes of providing a cost proposal, Offeror(s) shall provide a detailed budget based on the development and validation of one rodent model and one or more non-rodent small animal models. Include documentation for personnel costs and all specific animal, supply, and equipment costs.]

6. In the solicitation under Section J, the portion entitled, How to Prepare and Submit an Electronic Proposal, is amended to read as follows:

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS

FOR THE GENERIC PROPOSALS THERE IS **A 200 PAGE LIMITATION** FOR THE TECHNICAL PROPOSAL PORTION, INCLUSIVE OF APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-ELECTRONIC FIGURES OR DATA, LETTERS OF INTENT, ETC. ANY PORTIONS OF YOUR GENERIC PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THIS TOTAL PAGE LIMITATION. PROVIDE TEN (10) COMPLETE (UNBOUND) COPIES OF ANY NON-ELECTRONIC DOCUMENTS. IN DETERMINING WHETHER OR NOT TO INCLUDE ANY TECHNICAL PROPOSAL CONTENT, CONSIDER WHETHER OR NOT YOU BELIEVE THE NIAID WOULD REQUIRE THE DOCUMENTATION IN ORDER TO MAKE A COMPLETE EVALUATION OF THE PROPOSAL. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE GENERIC PROPOSAL(S) AND WILL NOT BE READ OR EVALUATED. **NOTE THAT OFFERORS' GENERIC (TECHNICAL AND BUSINESS) PROPOSALS ARE TO BE SUBMITTED ELECTRONICALLY VIA THE NIAID INTERNET SITE. OFFERORS SHOULD CONTACT THE NAMED CONTRACTING OFFICER FOR THIS SOLICITATION TO OBTAIN A LOG-IN AND PASSWORD FOR THIS PURPOSE.**

FOR TASK ORDER PROPOSALS THERE IS **A 150 PAGE LIMITATION** FOR THE TECHNICAL PROPOSAL PORTION, INCLUSIVE OF APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-ELECTRONIC FIGURES OR DATA, LETTERS OF INTENT, ETC. ANY PORTIONS OF YOUR TASK ORDER PROPOSAL(S) NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THIS TOTAL PAGE LIMITATION. PROVIDE TEN (10) COMPLETE (UNBOUND) COPIES OF ANY NON-ELECTRONIC DOCUMENTS. IN DETERMINING WHETHER OR NOT TO INCLUDE ANY TECHNICAL PROPOSAL CONTENT, CONSIDER WHETHER OR NOT YOU BELIEVE THE NIAID WOULD REQUIRE THE DOCUMENTATION IN ORDER TO MAKE A COMPLETE EVALUATION OF THE PROPOSAL. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE TASK ORDER PROPOSAL(S) AND WILL NOT BE READ OR EVALUATED. **NOTE THAT OFFERORS' TASK ORDER PROPOSALS (TECHNICAL AND BUSINESS) ARE TO BE SUBMITTED IN HARD COPY ONLY, ONE ORIGINAL AND FIVE (5) COPIES, EACH UNBOUND.**

NOTE THAT ALTHOUGH NO PAGE LIMIT HAS BEEN PLACED ON THE BUSINESS PROPOSALS FOR EITHER THE GENERIC OR TASK ORDER PROPOSALS, OFFERORS ARE ENCOURAGED TO LIMIT ITS SIZE AND CONTENT TO ONLY THOSE DOCUMENTS NECESSARY TO PROVIDE ADEQUATE SUPPORT FOR THE PROPOSED COSTS.

7. Offerors should refer to SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS, BUSINESS PROPOSAL INSTRUCTIONS, for what information should be included in their business proposals for both the generic Part(s) and for any of the individual task order proposals submitted. Offerors are also reminded to read and follow the Notes to All Offerors AND the Notes to Offerors associated with each generic Part as they prepare their generic technical and cost proposals. Also, Offerors are to ensure that they address all five (5) elements of the General Statement of Work for all Parts in each generic proposal submitted. Offerors should refer to Attachment (1) to this Amendment, which provides the NIAID's ANNUAL estimate of effort and some uniform budget assumptions for each generic Part, in preparing the cost (budget) portion of their business proposals for the generic Parts. Offerors are to build a seven (7) year budget for each generic Part for which they propose. The annual estimates in Attachment (1) are not mandatory. They are provided as a guide for the preparation of generic proposals. Note that Attachment (1) to this Amendment supercedes and replaces the Estimate of Effort table provided under SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS in the original solicitation.

For the task order business proposals, Offerors are reminded to address all the requirements contained in each of the twelve task orders and to adhere to the Notes to Offerors specifically related to each task order. Also, each task order contains at least one (1) Note to Offeror that should be read and followed in preparing individual task order proposals. Further, Offerors are to ensure that they address all five (5) elements of the General Statement of Work for all Parts in each task order proposal submitted. Offerors are to build a three (3) year budget for each of the task order proposals they submit.

8. Under SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS, BUSINESS PROPOSAL INSTRUCTIONS, Separation of Technical and Business Proposals, the paragraph is changed to read as follows:

The generic and the task order proposals must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. There should be NO cost information provided within either the generic or the task order technical proposals. The technical proposals should disclose the Offeror's technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions contained in this solicitation.

9. The following full text clause is hereby added to the solicitation Under SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct

discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

END OF MODIFICATION #2 TO RFP NIH-NIAID-DMID-03-39

ATTACHMENT (1)
To Amendment #2

ANNUAL ESTIMATE OF LABOR AND UNIFORM COST ASSUMPTIONS FOR EACH GENERIC PART

It is expected that multiple IDIQ contracts with cost-reimbursement completion type task orders will be awarded as a result of this RFP. To assist Offerors in the preparation of their generic proposals for each generic Part (A through F), the following year-1 (only) labor estimates and uniform cost assumptions are provided.

This information is for guidance and is not to be considered restrictive for proposal preparation purposes. Offerors are encouraged to utilize the assumptions stated in the Notes to Offerors regarding the preparation of the Generic cost proposal. Below, we are providing an annual estimate of effort (which NIAID estimated to be constant for all seven years) and estimated amounts for materials and supplies, travel, and renovation costs (where appropriate) for Year 1.
Offerors shall project costs for each of the 7 years, making sure to include any appropriate escalation in Years 2-7. For any labor categories that may contain more than one (1) full time employee, Offerors shall identify all employees to be utilized in that labor category and shall clearly identify the labor rate for each employee and any escalation applied to that rate in Years 2-7. Offerors are not bound to these figures; they are for guidance and they may be altered based on the assumptions in the Notes and any additional assumptions made by the Offerors. However, if the Offeror provides a cost proposal, which is significantly different from the guidelines provided below, it is expected that the Offeror will provide a narrative that completely explains any assumptions that they have made.

Offerors shall identify their indirect rates and amounts for each indirect rate, including, but not limited to, fringe benefits, overhead, material handling charges, general and administrative costs, etc. Any proposed profit/fee should be clearly identified as well.

GENERIC PART	LABOR CATEGORY	ANNUAL ESTIMATED DIRECT LABOR
A	Principal Investigator	15%
	Professional Staff	50%
	Senior Technician	100%
	Technical Support	200%
	Clerical Support	20%
	TOTAL	385%
Total Direct Labor Costs	Offeror to input amounts	
Fringe Benefits	Offeror to fill in rate and amounts	
Indirect Costs	Offeror to fill in rate and amounts	
Materials & Supplies	$135,000	
Travel	$ 3,000	
Renovation Costs	$200,000 (This is a “fixed” amount.)	
Other Direct Costs	Offeror to input amounts	
Fixed Fee	Offeror to input amounts	
Total Costs	Offeror to input amounts	

GENERIC PART	LABOR CATEGORY	ESTIMATED YEAR-1 EFFORT
B	Principal Investigator/Project Director	15%
	Professional Staff	50%
	Senior Technician	100%
	Technical Support	200%
	Clerical Support	15%
	TOTAL	380%
Total Direct Labor Costs	Offeror to input amounts	
Fringe Benefits	Offeror to fill in rate and amounts	
Indirect Costs	Offeror to fill in rate and amounts	
Materials & Supplies	$135,000	
Travel	$ 3,000	
Renovation Costs	$200,000 (This is a “fixed” amount.)	
Other Direct Costs	Offeror to input amounts	
Fixed Fee	Offeror to input amounts	
Total Costs	Offeror to input amounts	

GENERIC PART	LABOR CATEGORY	ESTIMATED YEAR-1 EFFORT
C	Principal Investigator/Project Director	20%
	Professional Staff	100%
	Animal Supervisor	80%
	Technical Support	100%
	Clerical Support	100%
	TOTAL	400%
Total Direct Labor Costs	Offeror to input amounts	
Fringe Benefits	Offeror to fill in rate and amounts	
Indirect Costs	Offeror to fill in rate and amounts	
Materials & Supplies	$245,000	
Animals	$121,600	
Travel	$ 3,000	
Renovation Costs	$300,000 (This is a “fixed” amount.)	
Other Direct Costs	Offeror to input amounts	
Fixed Fee	Offeror to input amounts	
Total Costs	Offeror to input amounts	

GENERIC PART	LABOR CATEGORY	ESTIMATED YEAR-1 EFFORT
D	Principal Investigator/Project Director	25%
	Professional Staff/Veterinarian	75%
	Senior Laboratory Investigator	50%
	Animal Supervisor	50%
	Technical Support	150%
	Clerical Support	200%
	TOTAL	550%
Total Direct Labor Costs	Offeror to input amounts	
Fringe Benefits	Offeror to fill in rate and amounts	
Indirect Costs	Offeror to fill in rate and amounts	
Materials & Supplies	$155,000	
Animals	$560,000	
Travel	$ 3,500	
Renovation Costs	$400,000 (This is a “fixed” amount.)	
Other Direct Costs	Offeror to input amounts	
Fixed Fee	Offeror to input amounts	
Total Costs	Offeror to input amounts	

GENERIC PART	LABOR CATEGORY	ESTIMATED YEAR-1 EFFORT
E	Principal Investigator/Project Director	25%
	Project Leader/Veterinarian	40%
	Professional Staff	75%
	Senior Technician	100%
	Technical Support	300%
	Clerical Support	20%
	TOTAL	560%
Total Direct Labor Costs	Offeror to input amounts	
Fringe Benefits	Offeror to fill in rate and amounts	
Indirect Costs	Offeror to fill in rate and amounts	
Materials & Supplies	$128,000	
Animals	$140,000	
Travel	$ 3,000	
Renovation Costs	Not Applicable	
Other Direct Costs	Offeror to input amounts	
Fixed Fee	Offeror to input amounts	
Total Costs	Offeror to input amounts	

GENERIC PART	LABOR CATEGORY	ESTIMATED YEAR-1 EFFORT
F	Principal Investigator/Project Director	30%
	Project Leader/Veterinarian	40%
	Professional Staff	100%
	Senior Technician	100%
	Technical Support	400%
	Clerical Support	30%
	TOTAL	700%
Total Direct Labor Costs	Offeror to input amounts	
Fringe Benefits	Offeror to fill in rate and amounts	
Indirect Costs	Offeror to fill in rate and amounts	
Materials & Supplies	$145,000	
Animals	$225,000	
Travel	$ 3,000	
Renovation Costs	Not Applicable	
Other Direct Costs	Offeror to input amounts	
Fixed Fee	Offeror to input amounts	
Total Costs	Offeror to input amounts	